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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,363	10/27/2003	Leanne M. Schrecengost	P-5218D1	2033

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EXAMINER

BULL, CHRISTOPHER

ART UNIT PAPER NUMBER

1655

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/694,363	<b>Applicant(s)</b> SCHRECENGOST ET AL.	
	<b>Examiner</b> Christopher Bull	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 Oct 2003 & 28 Feb 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-6 and 10-15 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-6 recite ranges of magnesium sulfate and SDS expressed in absolute quantity (i.e., micrograms). This method is done in solution where concentration is the controlling parameter, but it is unclear into what volume the claimed amounts are to be added (e.g., final assay volume, or volume of anionic substance solution to add).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Simpson et al. (US 5,004,684 issued 2 Apr 1991).

Claim 1 recites a method of extracting ATP comprising: a) introducing a cationic extractant and an anionic substance; and b) extracting ATP. Claims 10-11 recite reagents for this method, optionally comprising luciferin, luciferase and magnesium. Claim 15 recites a kit for this method.

Simpson et al. teach (Examples 2 and 3) a method for extracting ATP from microorganisms using benzethonium chloride, prepared in assay buffer (Example 1) comprising HEPES and EDTA, both of which are anionic substances at pH 7.75, and further assaying for ATP using luciferin, magnesium and luciferase (see Col 1 lines 52-62). Assay kits are contemplated (Col 6, lines 33-34).

Accordingly, the cited reference is deemed to anticipate the inventions of Claims 1, 10-11 and 15.

Claims 1 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundin (US 5,558,986 issued 24 Sept 1996).

Claim 1 recites a method of extracting ATP comprising: a) introducing a cationic extractant and an anionic substance; and b) extracting ATP. Claims 10-11 recite reagents for this method, optionally comprising luciferin, luciferase and magnesium. Claim 15 recites a kit for this method.

Lundin teaches (Col 9 lines 1-13) a method for extracting ATP from microorganisms using benzalkonium chloride, prepared in an assay buffer comprising Tris -Acetate and EDTA, both of which are anionic substances at pH 7.75, and further

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assaying for ATP using luciferin, luciferase and magnesium (Col 9 lines 17-19). Assay kits of their reagents (optionally dried onto a matrix) are contemplated (Claims 5 and 6).

Accordingly, the cited reference is deemed to anticipate the inventions of Claims 1, and 10-15.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 10-11, and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Shultz et al. (US 6,703,211 filed 15 Sept 1999).

Shultz et al. teach (Example 23) an ATP assay using Polymixin B and  $MgSO_4$  along with luciferin and luciferase. Shultz et al. teach (Column 7, lines 33-44) that Polymixin B is commonly referred to as an "extractant" in the context of cell lysis for a luminescent ATP measurement. Shultz et al. discuss a test kit for detection of ATP in a sample, comprising a cationic extractant and an anionic substance (Col 12, lines 1-26).

Claim 1 recites a method of extracting ATP comprising: a) introducing a cationic extractant and an anionic substance; and b) extracting ATP. Since polymixin B is a cationic extractant and the sulfate in magnesium sulfate is an anionic substance (as is the mononucleotide AMP also included by Shultz et al.), and since the context is

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extracting ATP from a cell for assay, the reference reads upon Claim 1, parts a and b. Shultz et al. also read on Claims 2-4 drawn to methods using magnesium sulfate, on Claims 10-11 drawn to reagents for extracting ATP, comprising a cationic surfactant, an anionic substance, luciferin, luciferase, and magnesium, and on Claim 15 drawn to a kit comprising a cationic extractant and an anionic substance.

Accordingly, the cited reference is deemed to anticipate the inventions of Claims 1-4, 10-11 and 15.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 10-11, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al.

The teachings of Schultz et al. with regard to Claims 1-4, 10-11, and 14-15, discussed above, are applied as before, particularly use of  $\text{MgSO}_4$  (see Example 23 Col 40 line 29).

Schultz et al. did not use the absolute amount of  $\text{MgSO}_4$  within the range recited by Claim 5.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention, while adjusting the volume of the assay of Schultz et al. as required by circumstance, to use an amount of  $\text{MgSO}_4$  within the instantly claimed range which results in the concentration of  $\text{MgSO}_4$  in the assay as taught by the reference, because it is conventional to adjust the scale of an assay as required.

One would have been motivated to do so for the expected benefit of economy given by the use of smaller volume assays, and by the ongoing trend in miniaturization of assay methods.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Aegidius (US 5,258,825 issued 2 Nov 1993) teaches an extraction medium containing cationic surfactants, including benzalkonium chloride with added magnesium sulfate, luciferin and luciferase.

Squirrell (US 5,648,232 issued 15 July 1997) teaches methods to extract ATP from cells using cationic detergents and phosphate buffers, with reagents and kits therefor.

Andreotti (US 5,916,802 issued 29 June 1999) teaches chlorhexidine acetate as extraction reagent, to be mixed with magnesium sulfate, luciferin, and luciferase as part of a swab assay for ATP.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Bull whose telephone number is (571) 272-1327. The examiner can normally be reached on 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0774. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Bull  
Patent Examiner  
Art Unit 1655

cb

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER